REMARKS

FORMAL MATTERS

No amendments have been made to the description or claims; only the abstract has been amended. The abstract is amended, as described above, to more closely reflect the language of the claims.

No new matter is added.

REJECTIONS TO THE SPECIFICATION

The Examiner appears to reject the abstract by reminding the applicant of the proper language and format for an abstract. Applicant herewith encloses an amended abstract which is believed to conform to the requirements for an abstract. The Examiner is respectfully requested to withdraw the rejection.

REJECTIONS UNDER § 112, SECOND PARAGRAPH

The Examiner rejected claims 1, 3-5 and 7-11 for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner states that the claims are incomplete for omitting essential structural cooperative relationships of elements and guides the Applicant to MPEP § 2172.01. Applicant respectfully disagrees. MPEP § 2172.01 states

> A claim which omits matter disclosed to be essential to the invention *as described in the specification or in other statements of record* may be rejected under 35 U.S.C. 112, first paragraph, as not enabling...
>
> In addition, a claim which fails to interrelate essential elements of the invention *as defined by applicant(s) in the specification* may be rejected under 35 U.S.C. 112, second paragraph, for failure to point out and distinctly claim the invention. [Emphasis added]

Notwithstanding that the Examiner does not specifically point out the location in the specification or other statement of record of the allegedly essential subject matter, Applicant respectfully submits that all essential elements as set out in the specification and other statements of record are set out in the enclosed claims. In particular, that applicant advises that there is nothing essential to the invention that is not the drug and the polymer and for clarity, it is not essential for the uncoated particles to have a coating as suggested by the Examiner. Furthermore, it is not clear whether the Examiner intended to reject the claims under § 112 second paragraph or § 112 first paragraph. While the quotation from the statute is that of § 112 second paragraph, the language used by the Examiner in the rejection appears to refer to rejections under §112 first paragraph, in which case Applicant advises that the subject matter of claim 1 is fully supported and enabled by the description of the invention. The Examiner is respectfully requested to withdraw the rejection.

REJECTIONS UNDER § 103(A)

The Examiner maintained the rejection of claims 1, 3 and 4, alleging that Devane *et al.* would be interpreted by one of skill in the art as teaching that two granular populations containing the same active agent, may be construed as a single granular population wherein the first and second populations comprise the same polymers and since there is a list of polymers that are identified as suitable for use as modified release matrix material by Devane *et al.*, including methylcrystaline cellulose and PVAP and since Example 2 of Devane *et al.* teaches compositions comprising methylphenidate and methylcrystaline cellulose that this allegedly renders the present invention obvious. The Applicant respectfully disagrees. The present invention comprises, in essence, methylphenidate and PVAP. Applicant submits that nowhere in Devane *et al.* is it taught or suggested that a composition may have only two ingredients (the active ingredient and a single polymer) homogenously mixed into a single population of granules.

It is made clear throughout the teachings of Devane *et al.* that a composition must comprise two granular populations, each population containing an active ingredient. Those two populations are 1) a population comprising an immediate release formulation of active ingredient

and 2) a population comprising a modified release of active ingredient. All of the examples of Devane *et al.* teach that a population of immediate release granules is mixed with a population of modified release granules. Column 10, lines 36 to 38 of Devane *et al.* state:

> The composition according to the invention comprises at least two populations of active ingredient containing particles which have *different in vitro dissolution profiles*. [Emphasis added]

The reason for compositions described in Devane *et al.* comprising two such populations having different in vitro dissolution profiles is described at column 10, lines 39 to 44 where the following is stated:

> Preferably, in operation the composition of the invention and the solid oral dosage forms containing the composition release the active ingredient such that substantially all of the active ingredient contained in the first component is released prior to release of the active ingredient from the second component.

The invention claimed in the present application comprises only one homogeneous population of granules in which each of the particles would necessarily have the same in vitro dissolution profile compared to each other particle in the composition since each particle has the same composition. There is nothing in Devane *et al.* that teaches, suggests or provides motivation to explore a single population of uncoated particles to prepare a homogenous mixture consisting essentially of a water-soluble drug and an enteric polymer in a ratio greater than 4 and less than 100 in order to provide a composition for oral administration which achieves drug release in two spikes, as set out in the claims of the present application.

The Examiner alleges that Example 1 teaches formulations of methylphenidate hydrochloride mixed with different functionally equivalent release coatings such as polyvinyl pyrrolidone and Eudragit®. This is not accurate. Example one teaches formulations of methylphenidate hydrochloride mixed with different release coatings such as polyvinyl pyrrolidone and Eudragit®, but it does not suggest that the different coatings are interchangeable

nor substitutable as between modified and immediate release populations. While Devane *et al.* does teach that both polyvinyl pyrrolidone and Eudragit® may be used in modified release compositions and that polyvinyl pyrrolidone may be used in immediate release compositions, it does not suggest that the same quantities and amounts of said polymers, or even that all of the same polymers may be used in both immediate release and modified release. Indeed there is no description or examples of a population that may be used as a modified release population in one formulation that may also be used as an immediate release population in another formulation or *vice versa*. It is clear from the teachings of Devane *et al.* that the compositions described therein comprise two populations of granules have different ingredients and ratios thereof as well as different dissolution profiles. This is quite unlike the formulations of the present invention in which there is a single population of uncoated particles in a homogeneous mixture. The Examiner is respectfully requested to withdraw the objection.

The Examiner further rejected all of the claims presently on file under 35 U.S.C. 103(a) as being allegedly unpatentable over Devane *et al.* In addition to the arguments provided above, the Applicant also submits the following. The Examiner alleges that in view of the examples, and the teachings of claims 1 and 6 of Devane *et al.* a person skilled in the art would be motivated to create two populations having the same ingredients but with different ratios thereby demonstrating bimodal release. Even if this were true, which, for clarity, the Applicant does not believe for the reasons discussed above, such a composition would not fall within the claims of the present application and therefore would be irrelevant.

Applicant submits that the Examiner is failing to view the present invention as a whole as required by 35 U.S.C. 103. In *Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d 1371 (Fed. Cir. 2005), there was expert testimony that the use of the claimed surfactant was obvious to substitute for other nonionic surfactants in the prior art. The Federal Circuit, while remanding the case for reconsideration of the testimony because of other issues, noted that "the bare question of whether it would have been obvious to substitute one surfactant for another misplaces the proper focus on the obviousness of the invention as a whole, and likely invites hindsight conclusion, forbidden by our precedent." Applicant notes that the present invention is directed to a composition for oral administration which achieves drug release in two spikes, said composition comprising a single

population of uncoated particles of a homogenous mixture consisting essentially of a water-soluble drug and an enteric polymer, wherein the ratio of enteric polymer to the water-soluble drug in the single population is greater than 4 and less than 100. The Examiner is respectfully requested to withdraw the rejection.

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CONCLUSION

The pending claims are believed to satisfy all of the criteria for patentability and are in condition for allowance. An early indication of the same is therefore kindly requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided below.

No fees beyond those submitted herewith are believed to be due in connection with this communication. However, the Commissioner is authorized to charge any underpayment of fees associated with this communication under 37 C.F.R. §§ 1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-4648, order number **PT2099001.**

Respectfully submitted,
APOTEX INC.

Date: February 23,2009

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this communication having 15 pages in total (1 page of fax cover page; 1 page of PTO/SB/21; 1 page of PTO/SB/81; 1 page of PTO/SB/30; 1 page PTO/SB/22 and 10 pages of Response to Final Office Action; are being facsimile transmitted to the Patent and Trademark Office (571-273-8300) on the date shown below.

Graham J. K. McKinnon
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Signature _____ Date February 23, 2009